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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,457	01/05/2001	Anders Larsson	PL-9813	8539

26271 7590 05/23/2005
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EXAMINER

HANDY, DWAYNE K

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,457

Applicant(s)

LARSSON ET AL.

Examiner

Dwayne K. Handy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/10/05.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 42-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (6,143,248) in view of Burns et al. (6,379,929). This rejection was previously applied to claims 20-26, 31, 33, 36 and 42-47. This rejection is still in effect and now includes claims 48 and 49. Please see Response to Arguments below.

Response to Arguments

3. Applicant's arguments filed 2/22/2005 have been fully considered but they are not persuasive. The Examiner would first like to thank Applicant for the demonstration of Applicant's device during the interview on 2/16/2005.

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4. Applicant has requested that the Examiner produce a passage from Kellogg stating an inlet having a nanoliter of material. The Examiner concedes that Kellogg does not *specifically state the manipulation of a nanoliter-quantity of liquid*, but the Examiner believes the device to be capable of handling such an amount. Kellogg repeatedly refers to the addition of a fluid sample in an entry port having a volumetric capacity of 1 to about 100 (or 150) microliters. The Examiner believes this was well established by Applicant in the personal interview. Applicant then argued that the instant invention is defined over Kellogg because it is better suited for use with nanoliter-scale quantities since Kellogg did not specifically recite manipulation of samples that are less than 1 microliter. It was the position of the Examiner and his Supervisor at the time, however, that (1) Even though Kellogg did not mention the manipulation of nanoliter-scale quantities, the Examiner and his Supervisor did not feel that this excluded Kellogg from manipulating smaller amounts of material; (2) The supposed enhancement provided by Applicant's device when using nanoscale quantities was not reflected in the claimed structure of the device; and (3) Applicant may be required to show – through experimental evidence - that their device or method of using the device provides the enhancement as suggested by Applicant in the personal interview. This would include a showing that Kellogg could not indeed be used to manipulate nanoliter quantities as argued by Applicant.

Applicant's new limitation, however, appears to be drawn to limiting the size of the inlet "adding the liquid to an inlet.....wherein the inlet is capable of handling less than about 500 microliters of a liquid sample" – and not to any other structural element

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of the device that may distinguish. In addition, applicant has used the term "capable" which carries no patentable weight. (It has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.). The Examiner believes that an entry port "having a volumetric capacity of 1 to about 100 (or 150) microliters" is indeed capable of handling less than that amount. This would include nanoliter-scale quantities. Therefore, claims 42-49 are rejected.

As to the limitations in claims 42 and 43, the Examiner believes it would be obvious to one of ordinary skill in the art to provide a nanoliter of sample. One would use a smaller sample in order to conserve sample material. The Examiner also believes it would be obvious to one of ordinary skill in the art to provide reactants as well. In column 27, lines 15-23, Kellogg teaches treatment of a blood sample. The treatment includes addition of heparin to the biological fluid to prevent coagulation. It would have been obvious to one of ordinary skill in the art to add the reactant through the input port.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DKH
May 15, 2005


Jill Warden
Supervisory Patent Examiner
Technology Center 1700